REMARKS/ARGUMENTS

This Amendment is filed in response to the Office action that was mailed on September 26, 2008. Claims 1-3, 10, 12-19, 21-40, 42-50 and 60 are pending in this Application. Applicant respectfully requests reconsideration and allowance of all Claims in view of the following remarks.

Claim Rejections – 35 U.S.C. § 103

Beginning on page 2 of the Office action, Claims 1, 10, 12 and 31-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,350,278 to Lenker et al. (Lenker `278) in view of U.S. Patent No. 4,705,040 to Mueller et al. (Mueller `040). It is indicated in the Office action that Lenker `278 discloses all of the elements of Claim 1 except for the means for fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds said portion against said vessel wall, but that Mueller `040 does disclose this feature. Applicant respectfully traverses this rejection.

Claim 1 recites: "An apparatus for installing an implant in a hollow body organ having a vessel wall, including: means for transporting said implant into said hollow body organ; a removable expansion assembly releasably engageable with said implant...; means for dilating said expansion assembly and **expanding a portion of said implant against said vessel wall; means for fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds**

said portion against said vessel wall; and means for collapsing said expansion assembly and releasing said portion of said implant."

Applicant respectfully submits that Lenker `278 fails to disclose **means for** dilating the expansion assembly and **expanding a portion of the implant** against the vessel wall, as claimed in independent Claim 1. As depicted throughout Lenker `278, the implant of Lenker `278 is self-expanding. As such, there are no means disclosed within Lenker `278, or even required thereby, for expanding the implant. Instead, all that is required for the implant of Lenker `278 to expand is to remove a retaining structure, various designs of which are disclosed throughout Lenker `278. The implant of Lenker `278 then expands on its own.

Applicant also respectfully submits that, as acknowledged in the Office action, Lenker `278 fails to disclose means for fastening the implant to the vessel. The definition of "fastening," as defined on www.dictionary.com, is "to attach firmly to something else, as by pinning or nailing." Lenker `278 shows a self-expandable implant that expands into contact with the vessel wall, and thereby has no requirement to be fastened to the vessel wall. Moreover, having a self-expanding implant, the implant is likely intended to have no means to separately fasten it to the vessel. Additionally, those of skill in the art are unlikely to consider the fixation device of Mueller `040 as a means to fasten the implant of Lenker `278 to the vessel wall because the fastening device of Mueller `040 is meant to be used percutaneously. As disclosed in Mueller `040, the fixation device is intended to be used to fix a hollow organ, such as the

stomach, to a body wall, such as the abdominal wall (Mueller `040, column 1, lines 5-10, and Figures 3-4). If the fixation device of Mueller `040 were used in the manner taught therein (with the filaments positioned external the body) to fasten the implant of the present invention to the vessel wall, it would lead to increased stretching of the vessel wall as it pulls the vessel walls in various directions. To fasten the implant of Lenker `278 to the vessel wall using the fixation device of Mueller `040 in a manner similar to the present invention would require an open surgery, which Lenker `278 clearly teaches away from (Lenker `278, column 1, line 38 through column 2, line 16). The purpose behind self-expanding implant grafts, such as those of Lenker `278, is to avoid a full open surgery to place a graft and fasten the graft to the vessel wall from external the vessel. The present invention provides the benefits of fastening the graft to the vessel wall from external the vessel without full open surgery.

Based on the foregoing, Applicant respectfully submits that independent Claim 1 is allowable over Lenker `278 and that Mueller `040 does nothing to correct the deficiencies thereof. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 1 is respectfully requested. As Claims 2, 3, 10, 12-19 and 21-39 depend from independent Claim 1, Applicant also respectfully submits that they are allowable as depending from an allowable base claim and respectfully request that the rejection of these claims be reconsidered and withdrawn also.

Regarding Claim 10, it is indicated in the Office action that Lenker `278 discloses that the means for dilating the expansion assembly includes means for translating the central strut distally (FIGS. 23A-23B) to urge the end cap (344) to impinge on the proximal ends of the peripheral struts while holding the peripheral struts stationary or urging them in a proximal direction (FIG. 23B, item 350) to thereby compress the peripheral struts axially. Applicant respectfully traverses this rejection.

Applicant respectfully submits that nowhere in Lenker `278 does it disclose, teach or suggest that the means for dilating the expansion assembly includes means for translating the central strut distally to urge the end cap to impinge on the proximal ends of the peripheral struts while holding the peripheral struts stationary or urging them in a proximal direction to thereby compress the peripheral struts axially. Lenker `278 discloses the central strut being moved proximally (away from the surgeon) to release the proximal ends of the struts so that they may spring radially apart to release the implant (prosthesis P) from between the struts (Lenker `278 column 11, line 66 through column 12, line 10). However, there is no disclosure in Lenker `278 about inducing a compressive load on the struts of the retaining structure to cause the struts to expand radially outwardly. Indeed, Lenker `278 teaches away from such use of the retaining structure because such use of the retaining structure of Lenker `278 could not cause the prosthesis P to be released from the retaining structure. Based on the foregoing, Applicant respectfully submits that Claim 10 is allowable over Lenker `278. A

prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 10 is respectfully requested.

Regarding Claim 36, it is indicated in the Office action that Lenker `278 and Mueller `040 disclose all of the elements therein. Applicant respectfully traverses this rejection. Applicant respectfully submits that the elements of Claim 36 are not disclosed by Lenker `278 or Mueller `040, either together or individually. Regarding Claim 36, it is indicated in the Office action that Mueller `040 discloses that the invention has means for applying tensile force to the external portion of the at least one flexible tie connector, whereby the **implant and the vessel wall are clamped together** between the fastener member and the external portion of the at least one flexible tie connector. To be clamped together means to be compressed or held together, which requires opposing forces pressing the items together, not just being placed in juxtaposition with each other. Neither Lenker `278 nor Mueller `040, either together or individually, teaches or suggests how to clamp the implant and vessel wall together. As indicated above, Mueller `040 teaches the use of a fixation device to percutaneously fix a hollow organ, such as the stomach, to a body wall, such as the abdominal wall. Using such a method, it would be impossible to clamp the implant to the vessel wall. At best, the implant would merely be placed in juxtaposition to the vessel wall. Based on the foregoing, Applicant respectfully submits that Claim 36 is allowable over Lenker `278 in view of Mueller `040. A prima facie case of obviousness has not been established and

hence reconsideration and withdrawal of the rejection of Claim 36 is respectfully requested.

Beginning on page 5 of the Office action, Claims 2, 15, 24 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker `278 in view of Mueller `040, and further in view of U.S. Patent No. 4,728,328 to Hughes et al. (Hughes `328). Applicant respectfully traverses this rejection.

Claims 15, 24 and 25 each ultimately depend from Claim 2. Claim 2 recites: "The apparatus of claim 1, wherein said implant comprises a tubular, sleeve-like component free of mechanical structure." While Hughes `328 teaches a tubular, sleeve-like component free of mechanical structure, Applicant respectfully submits that the combination of Lenker `278, Mueller `040 and Hughes `328 does not teach or suggest the invention of Claim 2. As Lenker `278 discloses a self-expanding implant and an expansion assembly (retaining structure (340)) positioned externally of the implant to maintain the implant in a compressed condition until the implant is delivered to the deployment site, Lenker `278 would not lead one of ordinary skill in the art to replace the implant thereof with an implant having no mechanical structure or that is not self-expanding. Additionally, having the expansion assembly of Lenker `278 positioned externally of the implant of Hughes `328 would do nothing to expand the implant of Hughes `328 against a vessel wall when the expansion assembly is dilated, as recited in Claim 1 of the present Application.

Based on the foregoing, Applicant respectfully submits that Claim 2 is allowable over Lenker `278 in view of Mueller `040 and Hughes `328. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 2 is respectfully requested. As Claims 15, 24 and 25 depend from Claim 2, Applicant also respectfully submits that they are allowable as depending from an allowable base claim and respectfully request that the rejection of these claims be reconsidered and withdrawn also. Applicant also submits that Claims 2, 15, 24 and 25 are allowable as depending from an allowable independent claim.

Beginning on page 5 of the Office action, Claims 3 and 16-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker `278 in view of Mueller `040 and Hughes `328, and further in view of U.S. Patent Application Publication No. 2003/0023301 to Cox et al. (Cox `301). Applicant respectfully traverses this rejection.

Claims 3 and 16-19 depend from independent Claim 1. As indicated above, Claim 1 is believed to be allowable over Lenker `278 in view of Mueller `040. Claims 3 and 16-19 are, therefore, believed to be allowable as depending from an allowable base claim. Additionally, Applicant respectfully submits that Claim 3 is allowable over Lenker `278 in view of Mueller `040, Hughes `328 and Cox `301.

Claim 3 recites: "The apparatus of Claim 2, wherein said removable expansion assembly is disposed to translate concentrically **within** said tubular, sleeve-like component **free of mechanical structure."** Cox `301 teaches a **stent, which is completely a mechanical structure,** expanded by a balloon that is disposed therein.

Applicant respectfully submits that one of ordinary skill in the art would not be led to use the balloon of Cox `301 in conjunction with the fastening means of Mueller `040 because the balloon structure of Cox `301 would not work properly to hold a portion of the implant of Hughes `328 against a vessel wall while using the fastening means of Mueller `040 to fasten the implant to the vessel wall. The fastening means of Mueller `040 includes a needle that, when inserted into the vessel wall and the implant, would puncture the balloon structure of Cox `301 and cause it to rupture. With the balloon ruptured, the implant would collapse as the balloon would no longer be able to hold the implant against the vessel wall.

Based on the foregoing, Applicant respectfully submits that Claim 3 is allowable over Lenker `278 in view of Mueller `040, Hughes `328 and Cox `301. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 3 is respectfully requested.

Applicant also respectfully submits that Claim 17 is allowable over Lenker `278 in view of Mueller `040, Hughes `328 and Cox `301. Claim 17 recites: "The apparatus of Claim 16, wherein said first tube includes a lumen adapted to receive said tubular, sleeve-like component, said first tube having a diameter dimensioned so that the proximal end of said first tube engages said cuff in end-abutting relationship." Applicant respectfully submits that nowhere in any of Lenker `278, Mueller `040, Hughes `328 or Cox `301 does it disclose, teach or suggest that the first tube has a diameter dimensioned so that the proximal end of the first tube engages the cuff in end-abutting

relationship. Based on the foregoing, Applicant respectfully submits that Claim 17 is allowable over Lenker `278 in view of Mueller `040, Hughes `328 and Cox `301. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 17 is respectfully requested. As Claims 18 and 19 depend from Claim 17, Applicant respectfully submits that they are also allowable as depending from an allowable claim.

Beginning on page 6 of the Office action, Claims 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker `278 in view of Mueller `040 **as applied to Claim 7** and further in view of Cox `301. Applicant respectfully traverses this rejection.

Claim 7 was canceled in a previous amendment, and Claim 13 depends from Claim 1, making the scope of the rejection unclear. As far as the rejection refers to Claim 13, Lenker `287 does not teach the struts being retractable by pulling them into a tube, and it is unclear from Cox `301 that the tube would be capable of collapsing the struts of the device of Lenker `287. Based on the foregoing, Applicant respectfully submits that Claim 13 is allowable over Lenker `278 in view of Mueller `040 and Cox `301. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 13 is respectfully requested. As Claim 14 depends from Claim 13, Applicant respectfully submits it is also allowable as depending from an allowable claim.

Beginning on page 8 of the Office action, Claims 21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker `278 in view of Mueller `040 and Hughes `328 as applied to Claim 2, and further in view of U.S. Patent No. 5,607,466 to Imbert et al. (Imbert `466). Applicant respectfully traverses this rejection.

The rejection relies on Imbert `466 (column 6, lines 53-59) for the proposition that Imbert `466 teaches means for increased longitudinal stiffness, and said means including a plurality of stiffener struts secured in the sleeve. Imbert `466 (column 6, lines 53-59) recites: "In addition to catheter 2, there is also a stent 5 in vessel 1. Stent 5 is made of a permeable mesh of stiff intersecting fibers 6. The stiffness of fibers 6 is selected so that stent 5 will expand on its own due to its **radial elasticity** from a condition under tension with a small circumference into a relaxed state where it **supports the vascular wall with a uniform circumference** over its length." (Emphasis added.) Applicant respectfully submits that Imbert `466 does not teach or suggest means for increased longitudinal stiffness of the stent therein, but teaches **increased radial stiffness** of the stent for the purpose of supporting the vascular wall with a uniform circumference.

Based on the foregoing, Applicant respectfully submits that Claims 21 and 23 are allowable over Lenker `278 in view of Mueller `040, Hughes `328 and Imbert `466. Moreover, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claims 21 and 23 is respectfully requested. Additionally, Claims 21 and 23 depend from Claim 2, which in turn depends

from Claim 1. As indicated above, it is believed that Claims 1 and 2 are allowable. Applicant respectfully submits that Claims 21 and 23 are also allowable as depending from an allowable base claim.

Beginning on page 10 of the Office action, Claims 40 and 42-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenker `278 in view of Cox `301. Applicant respectfully traverses this rejection.

Claim 40 recites: "A removable expansion assembly for dilating a surgical implant within a hollow body organ, including: a plurality of peripheral struts, **said struts having a relaxed state in which said peripheral struts extend generally parallel to a longitudinal axis** and are spaced angularly thereabout ...." Lenker `278, however, teaches **struts (axial elements (342)) that are spring-loaded so that when the anchor (344) is moved distally (away from the surgeon) by advancing the shaft (350) (Lenker `278, FIG. 23b), the individual struts spring radially apart at the distal end** to release the prosthesis from the retaining structure (340) (Lenker `278, column 12, lines 1-10). In other words, the struts of Lenker `278 are positioned at an angle (sprung radially apart) to the longitudinal axis when in a relaxed state. For the struts of Lenker `278 to extend generally parallel to the longitudinal axis, they must be in a compressed state, not a relaxed state.

Based on the foregoing, Applicant respectfully submits that independent Claim 40 is allowable over Lenker `278 and that Cox `301 does nothing to correct the deficiencies thereof. Accordingly, a prima facie case of obviousness has not been

established and hence reconsideration and withdrawal of the rejection of Claim 40 is respectfully requested. As Claims 42-50 depend from independent Claim 40, Applicant also respectfully submits that they are allowable as depending from an allowable base claim and respectfully request that the rejection of these claims be reconsidered and withdrawn also.

Regarding Claim 60, it is not addressed in the claim rejections and is, therefore, presumed to be allowable over the cited art.

Conclusion

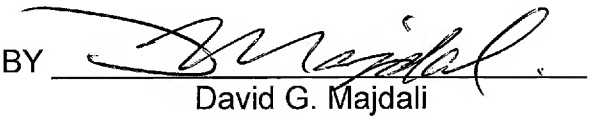
In view of the foregoing remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, reconsideration of the application and allowance of Claims 1-3, 10, 12-19, 21-40, 42-50 and 60 are respectfully requested. Applicant also respectfully submits that the noted features are merely exemplary and/or illustrative and does not disavow any claim scope or define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. Likewise, any characterization of the features in relation to the claims are merely exemplary and/or illustrative and thus Applicant does not disavow any claim scope or specially define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. Consequently, Applicant has not advanced every argument for the allowability of the claims over the references of record. As such, Applicant does not acquiesce to any of the Examiner's statements or

characterizations not specifically traversed. If the Examiner should have any remaining questions or objections, a telephone interview to discuss and resolve these issues is respectfully requested.

Please charge any additional fees, including any fees for additional extension of time, or credit any overpayment to Deposit Account No. 01-2215.

Sincerely

APPLIED MEDICAL RESOURCES

BY 

David G. Majdali
Reg. No. 53,257
Tel: (949) 713-8233